UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,831	09/22/2006	Toshihiro Akaike	69719.000003	3234

21967 7590 03/18/2009

HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
03/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,831	AKAIKE ET AL.	
	Examiner	Art Unit	
	SCOTT LONG	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *2* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/22/2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/22/2006 & 10/1/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Examiner acknowledges the election, without traverse, of Group I (claims 1 and 3-10) directed to a method of growing pluripotent stem comprising cultured on surfaces coated with adhesion molecules, in the reply filed on 2 February 2009. Because the applicant explicitly elected without traverse, the restriction is made final.

Claim Status

Claims 1-10 are pending. However, claim 2 is withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 1 and 3-10 are under current examination.

Sequence Compliance

Sequence Listing and CRF have been received and are acknowledged by examiner. A statement that the Computer Readable Form (CRF) and the Sequence Listing are identical has been submitted and is acknowledged by examiner.

Oath/Declaration

The oath or declaration, having the signatures of all inventors, received on 25 March 2005 is in compliance with 37 CFR 1.63.

Specification

The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. The hyperlinks are located on page 5, line 23 and page 24, line 35. Appropriate correction is required.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed on 1 October 2007 and 31 May 2007 consisting of 3 sheets are in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

Priority

This application claims benefit as a 371 of a National Stage of PCT/JP05/06006, filed 23 March 2005. This application claims benefit as a foreign application JAPAN 2004-085393, filed 3/23/2004. The instant application has been granted the benefit date, 1 April 2004, from foreign application JAPAN 2004-085393, filed 3/23/2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 8-10 are dependent from canceled claim 2. There is insufficient antecedent basis for this limitation in the claim. If the base claim has been canceled, a claim which is directly or indirectly dependent thereon should be rejected as incomplete. (MPEP 608.01(n)). These claims will be examined as though they only depend from claim 1. Correction is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagaoka et al (Biotechnology Letters, 2002; 24: 1857-1862) [known hereinafter as Nagaoka1] and as evidenced by Nagaoka et al. (Cell Structure and Function, 2003; 28(4): 327, IP-53) [known hereinafter as Nagaoka2].

Claim 1 is directed to a method for growing pluripotent stem cells, comprising growing said pluripotent stem cells in a dispersed state while maintaining their

undifferentiated state and pluripotentency, in a liquid medium and culturing vessel including immobilize or coated on a substrate solid phase surface a molecule which is adhesive to said pluripotent stem cells, without using feeder cells. Nagaoka1 teach growing F9 teratocarcinoma cells in a liquid medium and in a culturing vessel having a E-cadherin-IgG Fc coated surface (page 1860, col.1). F9 carcinoma teratocarcinoma cells are an undifferentiated cell line derived from a mouse embryonal carcinoma that is frequently used as a model for studying differentiation and pluripotency. In Nagaoka1, the F9 cells were used as a control and were not the primary subject of interest in the Nagaoka1. However, Nagaoka2 indicates that F9 mouse teratocarcinoma-derived embryonal carcinoma cells cultured on immobilized E-cad-Fc [fusion protein of E-cadherin extracellular domain and Immunoglobulin G (IgG) Fc region] remained undifferentiated. No feeder cells were used in either reference. Since the F9 cells in Nagaoka1 were cultured under identical conditions as in Nagaoka2, the examiner asserts that Nagaoka1 inherently satisfies the limitations of claim 1.

Claim 3 is directed to the method of claim 1 or 2, wherein the molecule which is adhesive to said pluripotent stem cells is either a molecule that is expressed by said pluripotent stem cells or a molecule that is structurally homologous with said molecule and has homophilic binding ability with said pluripotent stem cells. Nagaoka1 describes the E-cad-Fc as creating a homophilic interaction of E-cadherins (abstract).

Claim 4 is directed to the method of claim 3, wherein the molecule which is adhesive to said pluripotent stem cells is a molecule belonging to the cadherin family. The molecule, E-cadherin, is a part of the cadherin family.

Claim 5 is directed to the method of claim 4, wherein said molecule belonging to the cadherin family is E-cadherin, or a molecule which has structural homology with said molecule, which comprises the EC1 domain and one or more domains from among the EC2 domain, EC3 domain, EC4 domain and EC5 domain and which has homophilic binding ability with said pluripotent stem cells. The molecule, E-cadherin, is a part of the cadherin family. Nagaoka1 describes the E-cad-Fc as creating a homophilic interaction of E-cadherins (abstract).

Claim 6 is directed to the method of claim 5, wherein said E-cadherin is obtained from a mammal. The extracellular domain of E-cadherin used in the fusion protein is from mouse E-cadherin (Nagaoka1, Figure 1, page 1858).

Claim 7 is directed to the method of claim 6, wherein said E-cadherin is obtained from a human or mouse. The extracellular domain of E-cadherin used in the fusion protein is from mouse E-cadherin (Nagaoka1, Figure 1, page 1858).

Claim 8 is directed to the method of claim 1 or 2, wherein the molecule which is adhesive to said pluripotent stem cells is fused with an immunoglobulin Fc region and is immobilized on said substrate solid phase surface via said Fc region. Nagaoka1 teach a fusion protein comprising E-cadherin extracellular domain and Immunoglobulin G (IgG) Fc region. Nagaoka1 teach "we have applied an engineered protein of E-cadherin extracellular domain and immunoglobulin G (IgG) Fc region because Fc region has the potentiality to stably adsorb to a plastic surface such as polystyrene and dimerize via the hinge region." (page 1857, col.2).

Claim 9 is directed to the method of claim 1 or 2, wherein said pluripotent stem cells are mammalian embryonic stem cells (ES cells) or embryonic germ cells (EG cells). The specification indicates "'Pluripotent stem cells' are defined as cells capable of prolonged or virtually indefinite proliferation in vitro while retaining their undifferentiated state, exhibiting normal karyotype (chromosomes) and having the capacity to differentiate into all cell types of the three germ layers (ectoderm, mesoderm and endoderm) under the appropriate conditions." (page 2, lines 29-35). The F9 mouse teratocarcinoma-derived embryonal carcinoma cells of Nakaoka have a polyoma-based plasmid that persists as an episome, but have a normal karyotype. These cells are capable of differentiation into virtually all cell types of the body. Therefore, the examiner concludes the F9 cells of Nakaoka satisfy the limitations of claim 9.

Claim 10 is directed to pluripotent stem cells produced by the method of claim 1 or 2. The examiner concludes the F9 cells of Nakaoka satisfy the limitations of claim 10.

Accordingly, Nagaoka et al. anticipated the instant claims.

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Amit et al. (Developmental Biology, 2000; 227: 271-278).

Claim 10 is directed to pluripotent stem cells produced by the method of claim 1 or 2. Amit et al. describe pluripotent stem cell lines. Because the method of claim 1 produces pluripotent stem cells which are indistinguishable from those of pluripotent stem cells produced by any another means, the examiner concludes that the structural limitations of claim 10 are satisfied.

Accordingly, Amit et al. anticipated the instant claims.

Conclusion

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Scott Long/
Patent Examiner, Art Unit 1633